



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

priced
M28237

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
FAX: (781) 279-1742

WARNING LETTER

NWE-26-99W

July 26, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert W. Hagopian
President
Medica Corporation
14 DeAngelo Drive
Bedford, MA 01730

Dear Mr. Hagopian:

During an inspection of your establishment located at 14 DeAngelo Drive, Bedford, MA on June 17 through July 2, 1999, our investigator determined that your establishment manufactures the EasyLyte Na/K/CL/LI analyzers. These analyzers are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

- Failure to validate your process for the Chloride Electrode, Half-Cast, P/N 001800-002, with a high degree of assurance and according to established procedures, (21 CFR 820.75). For example:

Your Validation Protocol for this Chloride Electrode, dated July 24, 1997, referenced [REDACTED] field study to be conducted on the [REDACTED] chloride electrodes. There was no documentation to indicate this study was ever conducted.

Your Validation Protocol for the Chloride Electrode, dated July 24, 1997, did not provide a clear description of how the study was to be performed, did not contain specific acceptance criteria, nor did it explain how the data was interpreted. We also note similar deficiencies in your recent Validation Study for the Potassium Electrode, Half-Cast, P/N 002681-001, dated June 8, 1998.

Your Validation Protocol for the Chloride Electrode, dated July 24, 1997, failed to include any reference to the detrimental effects that the Chloride electrode may have on the lithium electrode. This was noted as a potential problem as early as March 30, 1997, however, no effort was made during the validation to evaluate the effect on the lithium electrode.

We note that this half-cast electrode was introduced into the field on April 1997, prior to the validation being completed on August 20, 1997. We also noted the failure rate of this electrode rose from [REDACTED] in 1997 to [REDACTED] in 1998 and was [REDACTED] for the first quarter of 1999.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA Form 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

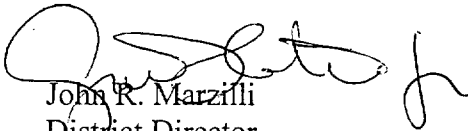
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We have received your letters dated July 2 and July 12, 1999 that were in response to your recent inspection. These responses do not provide a thorough response to the violations noted above nor do they explain the detailed steps your firm is making to prevent their recurrence. Therefore, please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure

taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Karen N. Archdeacon, Compliance Officer, Food and Drug Administration, One Montvale Avenue, Stoneham, MA 02180.

Sincerely yours,



John R. Marzilli
District Director
New England District